October 8, 2002

Kevin N. Baer, Ph.D.
Associate Professor of Toxicology
Deltech Corporation
700 University Avenue
Monroe, Louisiana 71209

Dear Dr. Baer:

The Office of Pollution and Toxics is transmitting EPA's comments on the robust summaries and test plan for p-Ethyltoluene posted on the ChemRTK HPV Challenge Program Web site on June 14, 2002. I commend Deltech Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Deltech Corporation advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: C. Auer
A. Abramson
W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
p-Ethyltoluene

SUMMARY OF EPA COMMENTS

The sponsor, Deltech Corporation, submitted a test plan and robust summaries to EPA, dated May 22, 2002, for p-Ethyltoluene (CAS No. 622-96-8). EPA posted the submission on the RTK HPV Challenge Website on June 14, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. EPA agrees with the test plan for these endpoints.

2. Health Effects. Adequate data are available for all endpoints for the purposes of the HPV Challenge Program.

3. Ecological Effects. EPA agrees with the test plan for these endpoints.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE p-ETHYLTOLUENE CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

The data provided for melting point, boiling point and vapor pressure are adequate for the purposes of the HPV Challenge Program; however, the method of determination and other experimental details were not provided. The submitter needs to provide this information.

Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

The test plan for these endpoints is adequate for the purposes of the HPV Challenge Program.

Transport and Distribution (fugacity). When developing the fugacity model estimates, the submitter needs to provide the assumption and data inputs to the model (see Guidance for Robust Summary preparation). Furthermore, in order to develop the fugacity model estimates, EPA recommends using a level III model. Although EPA had previously recommended the use of level I, this model is somewhat limited. EPA now recommends the use of level III, which provides a more rigorous level of analysis.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate existing data are available for all endpoints. EPA evaluated all of the submitter's genotoxicity study summaries (including those that the submitter described as not reviewed) and concluded that the data are adequate for both gene mutations and chromosomal aberrations.

Ecological Effects (fish, daphnid, and algal toxicity).

The test plan for these endpoints is adequate for the purposes of the HPV Challenge Program.

Specific Comments on Robust Summaries

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

The method of determination and other experimental details for melting point, boiling point, and vapor pressure were not provided in the robust summaries. The submitter needs to provide this information.

Health Effects.

Repeated-Dose Toxicity. Although the 13-week inhalation toxicity study was conducted according to EPA guidelines, it would be useful for the submitter to specify the organs that were examined.

Genotoxicity. The submitter should indicate whether the sister chromatid exchange assay in mouse bone marrow cells was performed up to a cytotoxic concentration.

Followup Activity

EPA requests that the Sponsor advise the Agency within 60 days of any modifications to its submission.